waste materials generated in the laboratories serviced by the contracts administered by FDA, if the waste is disposed of in compliance with all applicable Federal, State, and local requirements.

§ 25.31 Human drugs and biologics.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, if the action does not increase the use of the active moiety.

(b) Action on an NDA, abbreviated application, or a supplement to such applications, or action on an OTC monograph, if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.

(c) Action on an NDA, abbreviated application, application for marketing approval of a biologic product, or a supplement to such applications, or action on an OTC monograph, for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

(d) Withdrawal of approval of an NDA or an abbreviated application.

(e) Action on an IND.

(f) Testing and release by the Center for Biologics Evaluation and Research of lots or batches of a licensed biologic product.

(g) Establishment of bioequivalence requirements for a human drug or a comparability determination for a biologic product subject to licensing.

(h) Issuance, revocation, or amendment of a standard for a biologic product.

(i) Revocation of a license for a biologic product.

(j) Action on an application for marketing approval for marketing of a biologic product for transfusable human blood or blood components and plasma.

[62 FR 40592, July 29, 1997, as amended at 63 FR 26697, May 13, 1998; 64 FR 399, Jan. 5, 1999]

EFFECTIVE DATE NOTE: At 64 FR 399, Jan. 5, 1999, § 25.31 was amended by removing paragraph (f) and redesignating paragraph (g) as paragraph (f), and by removing paragraph (h), and by redesignating paragraphs (i) through (l) as paragraphs (g) through (j), effective May 20, 1999. For the convenience of the user, the superseded text is set forth as follows:

§ 25.31 Human drugs and biologics.

* * * * *

(f) Testing and certification of batches of an antibiotic.

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(h) Issuance, revocation, or amendment of a monograph for an antibiotic drug.

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§ 25.32 Foods, food additives, and color additives.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Issuance, amendment, or repeal of a food standard.

(b) Action on a request for exemption for investigational use of a food additive if the food additive to be shipped under the request is intended to be used for clinical studies or research.

(c) Approval of a color additive petition to change a provisionally listed color additive to permanent listing for use in food, drugs, devices, or cosmetics.

(d) Testing and certification of batches of a color additive.

(e) Issuance of an interim food additive regulation.

(f) Affirmation of a food substance as GRAS for humans or animals on FDA's initiative or in response to a petition, under parts 182, 184, 186, or 582 of this chapter, and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, if the substance or food ingredient is already marketed in the United States for the proposed use.

(g) Issuance and enforcement of regulations relating to the control of communicable diseases or to interstate conveyance sanitation under parts 1240 and 1250 of this chapter.

(h) Approval of a request for diversion of adulterated or misbranded food for humans or animals to use as animal feeds.

(i) Approval of a food additive petition, GRAS affirmation petition, or the granting of a request for exemption from regulation as a food additive under §170.39 of this chapter, when the substance is present in finished food-packaging material at not greater than 5 percdditive petition, GRAS affirmation petition, or the granting of a request for exemption from regulation as a food additive under §170.39 of this chapter, when the substance is to be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use.

(k) Approval of a food additive, color additive, or GRAS petition for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food.

(l) Approval of a petition for color additives used in contact lenses, sutures, filaments used as supporting haptics in intraocular lenses, bone cement, and in other FDA-regulated products having similarly low levels of use.

(m) Action to prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics.

(n) Issuance, amendment, or revocation of a regulation pertaining to infant formulas.

(o) Approval of a food additive petition for the intended expression product(s) present in food derived from new plant varieties.

(p) Issuance, amendment, or revocation of a regulation in response to a reference amount petition as described in §101.12(h) of this chapter, a nutrient content claim petition as described in §101.69 of this chapter, a health claim petition as described in §101.70 of this chapter, or a petition pertaining to the label declaration of ingredients as described in §101.103 of this chapter.

(q) Approval of a food additive petition or the granting of a request for an exemption from regulation as a food additive under §170.39 of this chapter for a substance registered by the Environmental Protection Agency under FIFRA for the same use requested in the petition.

(r) Approval of a food additive, color additive, or GRAS affirmation petition for a substance that occurs naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

§25.33 Animal drugs.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Action on an NADA, abbreviated application, or a supplement to such applications, if the action does not increase the use of the drug. Actions to which this categorical exclusion applies may include:

(1) An animal drug to be marketed under the same conditions of approval as a previously approved animal drug;

(2) A combination of previously approved animal drugs;

(3) A new premix or other formulation of a previously approved animal drug;

(4) Changes specified in §514.8 (a)(5), (a)(6), or (d) of this chapter;

(5) A change of sponsor;

(6) A previously approved animal drug to be contained in medicated feed blocks under §510.455 of this chapter or as a liquid feed supplement under §558.5 of this chapter; or

(7) Approval of a drug for use in animal feeds if such drug has been approved under §514.2 or 514.9 of this chapter for other uses.

(b) [Reserved]

(c) Action on an NADA, abbreviated application, or a supplement to such applications, for substances that occur naturally in the environment when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.